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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,955	02/28/2000	Stephen Paul Bryant	1581.059000/RWE	8701

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Bruce D. Grant
Morrison & Foerster LLP
3811 Valley Centre Drive
suite 500
San Diego, CA 92130-2332

EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/19/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/514,955

Applicant(s)

BRYANT ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-40 is/are rejected.
- 7) ☒ Claim(s) 52 is/are objected to.
- 8) ☒ Claim(s) 1-24 are cancelled.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 22 August 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 2 Sheets
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

APPLICANTS' ELECTION

Applicant election with traverse of Group III (drawn to a method of identifying a correlation between phenotype information and genotype information) and Species IA (directed to DNA sequence) is acknowledged. Applicants traversal argument is on the grounds that Groups III and XI are classified within the same class and subclass, therefore one search should cover the subject matter of Groups III and XI is found moot since claims 1-24 have been cancelled. However, upon evaluation of new claims 25-54 it is found that all new claims (directed to the above elected invention) will be examined.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 25-54. Claims 1-24 have been cancelled as indicated in Paper No. 10, filed 02 August 2002.

TITLE NOT DESCRIPTIVE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to a clinical and diagnostic database whereas in contrast the elected claims are to a method of identifying a correlation between phenotype information and genotype information.

FOREIGN PRIORITY

Applicants claim for priority under 35 U.S.C. § 119 (a)-(d) to Great Britain Patent Office Application No. 9904585.8 is acknowledged, wherein a certified copy is submitted.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

USE CLAIM

Claims 40-50 are rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example *Ex parte Dunki*, 153 U.S.P.Q. 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 U.S.P.Q. 475 (D.D.C. 1966).

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF ENABLEMENT

Claims 25-54 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required

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include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 25, 33, 39, 40, 48, and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as based on a disclosure which is not enabling. Applicants have set forth in claims 25, 33, 39, and 48 step(s) that are not provided for by the disclosure as to the procedures and/or limitations required for performing said step(s). Claim 25 (lines 4-5) indicates a step of “identifying records from a database for individuals that comply with the selected phenotype characteristic” (additionally, refer to the below 112 2nd Paragraph Rejection). Again, lacking in the disclosure are steps for performing the step(s) of “taking account of the confounding information” in claim 25 (line 7). Claims 33 (line 2) and 48 (lines 1-3) indicates the step wherein the “genotype information is selected from ... inferred nucleotide sequences”; it is uncertain how one would infer the nucleotide sequences. Claims 33 (lines 3-4) and 48 (lines 3-4) also recite that “a record of variation between a specified sequence on a chromosome of the individual compared to a reference sequence”, however, the disclosure fails to indicate what the references are for the “record of variation” and what the “reference sequence” is. Claim 39 (lines 1-2) recites “contact information would enable the individual to be

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contacted and retested in person”, which the disclosure fails to elaborate on how the contact information would be enabling. Further, it is unclear what genotype information is being collected (i.e. sequence of an individual’s entire genome; page 35, lines 7-12) and which particular polymorphisms are being detected.

Thus, the disclosure is not enabled and an individual skilled in the art would not understand how to perform any of the above steps unless some type of procedure(s) are set forth to provide guidance for the practice of the claimed invention.

Additionally, instant claim 40 and all claims dependent therefrom fail to indicate any steps for the method of correlating genotype and phenotype information with account taken of potential or actual confounding information instant 40 and all claims dependent therefrom (Refer to the below 35 U.S.C. § 112 2nd Paragraph Rejection), one of skill in the art would not be able to perform the invention as claimed. It is not known what type of correlation analysis or other analysis to perform to result in identifying the desired information. With respect to claims 28 and 43, the specification defines some but not all osteoporosis related phenotypes, osteoarthritis related phenotypes, immune cell subtypes (such as Tcell subsets), metabolic syndrome/syndrome X related phenotypes, and hypertension related phenotypes. With respect to claims 29, 44, and 53, the specification defines some but not all thrombosis/fibrinolysis phenotypes, haemoglobinopathy related phenotypes, and airway disease (asthma) phenotypes.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-54 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

MISSING ESSENTIAL STEPS

Claims 27 and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See M.P.E.P. § 2172.01. The omitted step is the construction of a database consisting of phenotype and confounding information collected at the same time from the individual. Not e that the independent claims implies that the database already exists.

Claims 40 and all claims dependent therefrom are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps (no steps are provide for), such omission amounting to a gap between the steps. See M.P.E.P. § 2172.01.

VAGUE AND INDEFINITE

Claim 25 and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is “a method of identifying a correlation between phenotype information and genotype information”, however the claim recites a final step of “taking account of the confounding information, determining if the presence of the selected phenotype characteristic is correlated with the presence of any genotype characteristic in the genotype

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information for records in the database”. There is no indication that a correlation between phenotype information and genotype information is intended to be identified as recited in the preamble. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when the a correlation is identified. That is, what statistical measure, if any, is required and what degree of correlation? Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claim 25 (line 4) and all claims dependent therefrom recite the term “comply” which is vague and indefinite. Applicants can resolve this issue by particularly pointing out the criteria(s), which are regarded as compliant; that is to “comply”. Clarification of the metes and bounds, via clearer claim wording is required.

Claims 28 (line 3) and 43 (line 3) recites the language “such as”, which is indefinite because it is unclear if “such as” imparts a particular limitation to the claim. Clarification is required, via clearer claim wording.

Claims 29 (line 3), 44 (line 3), and 53 (line 3) recites the language “(asthma)”, wherein the parentheses make it unclear whether this is a particular limitation. Clarification is required, via clearer claim wording.

Claims 36 (line 2), 51 (line 2), and all claims dependent therefrom recites the phrase “relating to the location of a sample of tissue or fluid from an individual” which is confusing. It is unclear whether the location of a sample is with respect to: 1) tissue location (claims 37 and 52); 2) geographical location (claim 52; i.e. address); or 3) both tissue location and geographical

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location. Applicants can resolve this issue by particularly pointing out the limitations of “location of a sample”, via clearer claim language.

Claim 40 (line 2) and all claims dependent therefrom recite the term “potential” which implies some criteria considered to be “potential” confounding information. Applicants can resolve this issue by particularly pointing out the criteria by which confounding information is considered “potential”. Clarification of the metes and bounds, via clearer claim wording is required.

Claims 39 (line 1-2) and 54 (lines 1-2) and all claims dependent therefrom recite the phrase “the sample information comprises contact information enabling the individual to be contacted and retested in person” which is vague and indefinite. Applicants can resolve this issue by particularly pointing out the limitations of the contact information that would enable the individual to be contacted and retested in person. Clarification of the metes and bounds, via clearer claim wording is required.

LACK OF ANTECEDENT BASIS

Claims 27 (line 2) and 28 (line 2) recites the limitation "individual", however, claim 25 (which claims 27 and 28 depend from) fails to indicated an “individual”. Thus, there is insufficient antecedent basis for this limitation in the claim. It should be noted that claim 25 does indicate identifying records from a database for individuals.

Claims 42, 43, and 46 recites the limitation "individual" or “individuals”, however, claim 40 (which claims 42, 43, and 46 depend from) fails to indicated an “individual” or “individuals”. Thus, there is insufficient antecedent basis for this limitation in the claim. Thus, there is insufficient antecedent basis for this limitation in the claim.

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Claim 54 recites the limitation “sample information” in line 1, however, claims 25 and 51 (which claim 54 depends from) fails to indicate the “sample information”. Thus, there is insufficient antecedent basis for this limitation in the claim.

USE CLAIM

Claim 40 (lines 2-4) and all claims dependent therefrom provides for the use of “a database comprising a plurality of records containing phenotype information, genotype information, and confounding information”, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-31, 33, 36, 37, 40-46, 48, 51-53 are rejected under 35 U.S.C. § 102 as being clearly anticipated by Perlin et al. (WO 95/21269).

Perlin et al. describes a method and apparatus for analyzing genetic material by high-throughput genotyping to assess risk for common multi-factorial diseases; wherein the genetic information obtained allows for the tracing of chromosomal segments within families and populations and phenotypic correlation (instant claim 25; Abstract; page 29, lines 12-28; and page 49, lines 14-27). Genotype information is obtained by extracting DNA from blood or

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various tissues (instant claims 33, 36, 37, 48, 51, and 52; page 32, lines 13-23). Phenotypic data comprised of history, physical data, laboratory data, phenotypic markers for various genetic diseases, and environmental exposures is gathered on individuals (regarded as human), animals, or plants (instant claims 26, 31, 41, 46; page 49-50, lines 28-31 and 1-3, respectively). As more genes are mapped the association between known genes with specific traits and diseases requires the techniques of genotyping and phenotyping correlation to identify disease genes (page 52-53, lines 27-30 and 1-17, respectively). The inventors illustrate the steps of obtaining phenotypic traits and genotypic information to determine the correlation between the data (instant claims 27, 40, 42; Figure 12). Risk of trait inheritance or disease is described as being determined through probabilistic techniques; thus "taking into account confounding information" (i.e. family history, environmental factors, etc.) (instant claims 25, 26, 40, and 41; page 52, lines 3-26 and Figure 12, step 8). The illustrated method is stated to work well with complex multi-genic multi-factorial diseases, such as cancer, heart disease, vascular disease, diabetes, glaucoma, and lung disease (instant claims 28-30, 43-45, and 53; pages 51-52, lines 17-31 and 1-2, respectively). Thus, Perlin et al. clearly anticipates the claimed invention.

OBJECTION TO CLAIM

Claim 52 is objected to for failing to have a period ending the claim.

OBJECTION TO DISCLOSURE

The disclosure is objected to because of the following informalities:

In the specification fails to provide a Brief Description of the Drawings. A separate brief description of each drawing is required.

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In the specification on page 11, line 26; page 12, line 21; and page 13, line 9 requires correction: “comprising:-“ should be corrected to “comprising:”

In the specification on page 13, lines 27-29, requires correction, wherein the sentence structure is confusing.

In the specification on page 15 requires correction: “gene” should be replaced with “gene;” (line 12); “Identification” should be replaced with “identification” (line 13); and “positions” should be replaced with “positions.” (line 18).

Appropriate Correction Is Required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *November 15, 2002*

Examiner Initials: *CSM*

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
-GROUP 1600

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